UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,046	02/01/2001	Johannes Eduard Maria Antonius Debets	DX01073K	3164

28008 7590 07/02/2002

DNAX RESEARCH INSTITUTE
LEGAL DEPARTMENT
901 CALIFORNIA AVENUE
PALO ALTO, CA 94304

EXAMINER
PRASAD, SARADA C

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 07/02/2002 8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/775,046	Applicant(s) ANTONIUS DEBETS ET AL.	
	Examiner Sarada C Prasad	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-3, drawn to a method of producing a ligand: receptor complex, comprising contacting a mammalian IL-1δ or IL-1ε with a receptor comprising the IL-1R6 receptor subunit, classified in class 435, subclass 7.1.

Group II. Claims 4-7, drawn to methods of modulating physiological signal by contacting an IL-1R6 receptor bearing cell with an antibody to IL-1δ, or antibody to IL-1ε, classified in class 435, subclass 7.1.

Group III. Claims 8-11, drawn to modulation of signal to a cell mediated by IL-1δ or IL-1ε comprising contacting the said cell with antibody to IL-1R6 receptor, classified in class 435, subclass 7.1.

Group IV. Claims 12-15, drawn to identification of cells by selectively labeling a population of cells with an IL-1R6 antibody, or a cytokine selected from IL-1δ or IL-1ε, and cells purified by the instant methods, classified in class 435, subclass 7.1.

Group V. Claims 16-17, drawn to a method of testing a compound for ability to affect IL-1R6 receptor-ligand interaction, said method comprising comparing the interaction of IL-1R6 with IL-1δ, or IL-1ε in the presence and absence of said compound, classified in class 435, subclass 7.1.

Group VI. Claims 18, drawn to isolated or recombinant polynucleotide of SEQ ID No. 1 encoding polypeptides of SEQ ID NO. 2, classified in class 435, subclass 69.1.

Group VII. Claims 18, drawn to isolated or recombinant polynucleotide of SEQ ID No. 3 encoding polypeptides of SEQ ID NO. 4, classified in class 435, subclass 69.1.

Group VIII. Claims 19, drawn to isolated or recombinant polypeptide of SEQ ID No. 2, classified in class 530, subclass 350.

Group IX. Claims 19, drawn to isolated or recombinant polypeptide of SEQ ID No. 4, classified in class 530, subclass 350.

Group X. Claim 20, drawn to a binding compound comprising an antigen-binding portion from an antibody, which binds with selectivity to SEQ ID. No.2, classified in class 530, subclass 387.7.

Group XI. Claim 20, drawn to a binding compound comprising an antigen-binding portion from an antibody, which binds with selectivity to SEQ ID. No.4, classified in class 530, subclass 387.7.

These inventions I-XI are each independent and distinct for the following reasons.

Inventions I-V are independent and distinct each from the other, because they are each completely different methods that involve different process steps and have independent uses. For example, Group I drawn to a method of producing a ligand receptor complex, which is not necessary in the practice of the inventions of Groups II-V. Furthermore, the different inventions II-V involving methods of modulating ligand receptor complex using antibodies to ligands (Group II), antibodies to receptor (Group III), or purification of cells based on identification of the agonist or antagonist or receptor (Group IV), or testing compounds for ability to affect IL-1R6 receptor-ligand interaction (Group V) are each distinct because these different methods of modulation of ligand-receptor complex formation, and the consequent signal transduction involves different reagents in each case, for example, antibodies to ligands (Group II), or antibodies to receptor (Group III), or candidate compounds that affect ligand receptor interaction

(Group V). Further, affinity based purification of cells based on affinity of antibodies directed to either ligand, or receptor in Group IV is distinct from modulation of physiological signals as in inventions of Groups II, III or V. For example, while assessing modulation of signal transduction one would monitor the endpoints, and no attempts to collect any particular cells is made. In contrast, during selective purification of cells based on labeling cells with either antibody directed to ligands, or receptors, the labeled cells are recovered, and may be used for further experimentation. Therefore, these methods of Groups I-V are each not necessary for the practice of the other.

Groups VI-XI are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent use, that is distinct for each invention which can not be exchanged. The nucleic acid of inventions VI and VII can be used to make hybridization probes or can be used in gene therapy for which polypeptides and binding agents cannot be used. The antibodies of Groups X and XI can be used in immunoassays, and to purify polypeptides for which the nucleic acids and polypeptides cannot be used.

Additionally, the polynucleotides of SEQ ID No. 1 and 3 (Groups VI and VII) and the polypeptides of SEQ ID Nos. 3 and 4 (Groups VIII and IX) are distinct each from the other, each having a completely different structure, and requiring a non-cohesive search and consideration.

Inventions VI-XI are related to inventions I-V as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case, the polypeptide products of inventions VIII-IX, and the antibody products of inventions X-XI can be used in performance of methods of inventions I-V. However, the antibodies and peptides may be used in materially different ways such as to purify polypeptides or to produce other antibodies.

Based on the above analysis, it is clear that Groups I-XI are patentably distinct, and require independent searches, and considerations. Further, these above inventions VI-XI are so grouped in order to have only one SEQ ID, either polynucleotide or polypeptide, in each Group for examination purposes. Furthermore, no matter which Group the Applicant elects, the Applicant is required to specify one specific nucleotide or polypeptide for examination. This requirement is made under 1192 O.G.68 Notice (November 19, 1996), as examination of more than one sequence in one application would result in an undue burden on the PTO.

Having shown that these inventions are distinct for the reasons given above, they have acquired a separate status in the art shown by their different classification, and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has prima facie shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarada C Prasad whose telephone number is 703-305-1009. The examiner can normally be reached Monday – Friday from 8.00 AM to 4.30 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sarada Prasad, Ph.D.
Examiner
Art Unit 1646
June 15th, 2002

YVONNE EYLER, PH.
SUPERVISORY PATENT
TECHNOLOGY CENTER